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December 26, 2012

**VIA ECF**

Honorable Tonianne J. Bongiovanni, U.S.M.J.  
U.S. District Court for the District of New Jersey  
Clarkson S. Fisher Building & U.S. Courthouse  
402 East State Street  
Trenton, New Jersey 08608

**Re:    *AstraZeneca AB, et al. v. Hanmi USA, Inc., et al.*  
      Civil Action No. 11-cv-0760 (JAP)(TJB)**

Dear Judge Bongiovanni:

This firm, along with Sughrue Mion, PLLC, represents the Hanmi Defendants (“collectively Hanmi”) in the above-captioned action. Hanmi respectfully submits this letter in response to the AstraZeneca Plaintiffs’ letter of Friday, December 21, 2012.

**Pretrial Schedule and Trial Date**

Hanmi first seeks to correct the record concerning the circumstances leading to the filing of Hanmi’s letter of December 20, 2012, requesting that the Court reset the pretrial schedule in view of the December 12, 2012 claim construction Order and Opinion (D.I. 259).

On November 28, 2012, Your Honor directed the parties to meet and confer regarding the pretrial schedule, so as to reset expert reports to be due, *e.g.*, 21 days from the claim construction ruling or that a further conference call be set with Your Honor immediately following the claim construction ruling to reset the dates (Nov. 28, 2012 Tr. 5-8). There was no contemplation of a “suspended” case schedule as AstraZeneca again proposes. Counsel for the parties met and conferred shortly thereafter, on December 5, 2012, with Hanmi proposing a fixed time following the ruling. AstraZeneca did not agree to any time frame for resetting the expert schedule and, following the December 12, 2012 issuance of the claim construction ruling, Hanmi on December 13, 2012 again proposed a pretrial schedule in compliance with the Court’s directives (*see* Ex. A, Boland to Rothman December 13, 2012 letter).



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AstraZeneca again refused to respond to Hanmi's proposed schedule. With a week having passed since the Court's December 12 claim construction ruling, and still no response from AstraZeneca, Hanmi on December 19, 2012 again wrote to AstraZeneca enclosing a proposed joint letter to the Court with the proposed expert schedule, indicating that Hanmi intended to file unilaterally on December 20, 2012 absent receipt of AstraZeneca's position on the expert schedule (Ex. B, Boland to Rothman December 19, 2012 letter).

Since AstraZeneca refused to negotiate a pretrial schedule despite the December 5 meet and confer and Hanmi's December 13 and 19 letters, Hanmi unfortunately was forced to submit a schedule unilaterally. AstraZeneca's statement that, "without discussing it with AstraZeneca, Hanmi unilaterally sent its letter" (AstraZeneca's December 21, 2012 letter to Court, p. 1) is incorrect and misleading.

AstraZeneca's December 21 letter effectively rejects an expert schedule altogether. The fact that AstraZeneca has enlisted Mylan in its efforts to delay this case should be given no weight since Mylan, as Hanmi's competitor, has every interest in delaying Hanmi's case lest Hanmi – having filed for FDA approval more than a year before Mylan – gain a commercial advantage over Mylan. In any case, based on the November 28 conference call with the Court, Hanmi understands that Judge Pisano is not inclined to try the *Mylan* and *Hanmi* cases together. The Court's *Markman* rulings now emphasize the further distinctions between the *Hanmi* and *Mylan* cases.

### **Alleged Remaining Claim Construction Issues**

AstraZeneca's motion for reconsideration of the Court's claim construction, filed late Friday, December 21, 2012, is certainly no basis to delay resetting the expert dates or trial. Hanmi will file its opposition shortly.

While AstraZeneca again asserts that Hanmi's October 15, 2012 Motion to Amend raises an issue of claim construction relating to "hydrates" and requires a further round of claim construction briefing, Hanmi disagrees. As counsel for the parties extensively discussed on December 5, as reflected in Hanmi's letter to AstraZeneca counsel on December 13 (Ex. A, Boland to Rothman December 13, 2012 letter), throughout this action, AstraZeneca had taken the position that hydrates are encompassed by the claims at issue, but changed that position during the briefing on Motion for Summary Judgment No. 4. Hanmi's amendments to its contentions merely serve to conform its contentions to the present case record, specifically in light of AstraZeneca's position in its opposition brief, and the Court's ruling on Motion for Summary Judgment No. 4. Hanmi relies on the present briefing on its Motion to Amend, and there is no need for "another round of claim construction briefing" on the hydrates issue. AstraZeneca already has Hanmi's full position and evidence, which is set forth in the Motion to Amend briefs – hydrated forms of esomeprazole salts are outside the scope of all asserted claims of both patents at issue. *See* Ex. A, Boland to Rothman December 13, 2012 letter.



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No discovery is needed on the issue of hydrates, as AstraZeneca has Hanmi's position in full, has responded in its opposition paper, and identified no need for any discovery necessary to respond to the motion. AstraZeneca's reference to its requests for admission served November 30, 2012 – ten days after the close of fact discovery and six weeks after the last date for serving written discovery – has nothing to do with the motion, as such requests belatedly and improperly seek discovery on various issues in the case.

### **Lindberg and Kohl Depositions**

AstraZeneca correctly advised that in view of Hanmi's agreement not to take now-retired inventor Lindberg's deposition, his prior deposition transcripts are now inadmissible in the present action. This agreement reflects the Court's indication that Hanmi's right to cross-examination of the witness is a prerequisite to admissibility of prior case transcripts.

With respect to the prior transcript of third party Kohl, AstraZeneca is unable to produce him for deposition by Hanmi, despite having previously used him as a Declarant in related proceedings. Thus, his transcript should be inadmissible in the present action. Hanmi does not intend to pursue involuntary discovery of Dr. Kohl through Hague-type proceedings in Germany, for the reasons set forth in Hanmi's letter to AstraZeneca of December 20, 2012 (Ex. C, Rathinam to Rothman December 20, 2012 letter). In short, pursuant to the Hague Convention, a German national unwilling to appear voluntarily for deposition, as is Dr. Kohl, is not subject to compulsory attendance. The limited rights to take discovery in Germany of an unwilling German national in U.S. civil litigation fall far short of the deposition Your Honor ordered that Hanmi is entitled to. Therefore, the prior Kohl transcript is clearly inadmissible since AstraZeneca's inability to produce Dr. Kohl for deposition denies Hanmi the fundamental right of cross examination. In any case, no depositions of either of these witnesses will be taking place, and thus no grounds for delay arise.

### **Belated and Irrelevant Discovery of Hanmi**

With respect to AstraZeneca's statements in section 5 at page 3 of its December 21 letter, such alleged need for belated discovery is no basis to delay setting the pretrial or trial schedules. As Hanmi's December 13, 2012 letter to AstraZeneca (Ex. D, Dzwonczyk to Rothman December 13, 2012 letter) made clear, fact discovery closed long before these requests and the discovery served was not only out of time but also unaccompanied by any of the required procedural prerequisites to serving belated discovery. Moreover, the 30(b)(6) topics fail to seek information relevant to any issue in this case.

### **Third Party Discovery of Parexel**

AstraZeneca waited until August 2012 to subpoena third party Parexel, despite knowing since April 2011 that Parexel submitted documents to the FDA on behalf of Hanmi. Any issues in completing this discovery should have been resolved long before the November 20, 2012 fact discovery cut-off. In any case, any such discovery will be duplicative of discovery AstraZeneca



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has taken directly from Hanmi during the discovery period concerning Hanmi's accused products and proceedings before the FDA. Hanmi continues to have no objection to AstraZeneca deposing Parexel out of time and supplementing its submissions if necessary. However, AstraZeneca should not be permitted to use its own delays in seeking discovery from a third party and then following up on that discovery to delay the trial rights of a Hatch-Waxman defendant facing expiration of the 30-month stay in six months.

Hanmi respectfully requests that its proposed pretrial schedule be adopted, and remains available to discuss the same with the Court if desired.

Respectfully,

*/s/ Mayra V. Tarantino*

Mayra V. Tarantino

MVT:emp

cc: Counsel of Record (via ECF)

# EXHIBIT A



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**Mark Boland**

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December 13, 2012

**Via Email**

Joshua I. Rothman, Esq.  
FITZPATRICK, CELLA, HARPER & SCINTO  
1290 Avenue of the Americas  
New York, NY 10104-3800

Re: *AstraZeneca AB et al. v. Hanmi USA, Inc. et al.*,  
Civil Action No. 11-00760 (JAP)(TJB)

Dear Josh:

This follows our conversation on December 5<sup>th</sup> about Hanmi's Motion to Amend, and the proposal in your letter of December 7<sup>th</sup> including a schedule for additional claim construction briefing.

As I explained to you in detail, there is no need for another *Markman* track on the hydrates issue. Throughout the case AstraZeneca took the position that hydrates were encompassed by the claims at issue, but changed its position during the briefing on Motion for Summary Judgment No. 4. In light of AstraZeneca's new position in its opposition brief and the Court's ruling, the main issues raised by our request to amend is simple – if hydrates are outside the scope of the claims, we should be entitled to assert non-infringement due to the changed circumstances of the case; in any case, we have modestly amended our invalidity contentions to address the issue of “later-developed technology” expressed in your summary judgment opposition, but not in your prior contentions.

Since you have characterized our Motion as raising a claim construction issue, in terms of exchanging terms for construction, you have our position – on the present litigation record, hydrated forms of esomeprazole salts are outside the scope of all asserted claims of both patents at issue. You have our evidence too – that is summarized in the briefing on the pending Motion to Amend. Judge Bongiovanni advised us to address any discovery needed on the issue, but none is necessary since you have our position in full, and you have responded in your opposition paper. Thus, the opening two dates in your proposal are unnecessary, and the merits have already been briefed.

In a nutshell, you have proposed another *Markman* track – we appreciate that it is abbreviated – but you previously argued the need for this schedule as grounds to delay the trial date. If you truly believe that additional briefing is required as to whether or not hydrates are



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covered by the claims, we will agree to your proposal of supplemental cross-briefs during the upcoming expert discovery period on the conditions that (1) AstraZeneca withdraws its opposition to the Motion to Amend, as you have represented, (2) you agree not to use any agreed proposal for further briefing as a basis to urge delay of the April / early May trial timeframe, and (3) you agree not to seek to delay the trial for other reasons, now that we have the Court's *Markman* decision and fact discovery has concluded, except for a couple of wrap-up issues addressed in other communications. You can choose the cross-briefing dates to propose to the Court if you agree to these straightforward conditions; we only ask that they be limited to, *e.g.*, ten pages each.

We must emphasize, however, that if further briefing (on whether or not hydrates are inside or outside the scope of the asserted claims of the two patents) is suggested to the Court and adopted, Hanmi's position will simply mirror the position taken in the Motion to Amend, and since you have already responded, such additional briefing will largely be redundant, and thus not in the interests of economy, and not likely to be agreed to by the Court since the issue is squarely teed up in briefs already before the Court.

In view of yesterday's *Markman* decision, and Judge Bongiovanni's admonition that the parties may need to condense the expert discovery schedule to accommodate the spring trial in view of the date of the decision, we propose that opening expert reports are due January 7<sup>th</sup>, responsive reports are due January 28<sup>th</sup>, reply reports are due February 11<sup>th</sup>, and expert depositions conclude by March 4<sup>th</sup>. This merely takes one week off of each current expert discovery deadline, would put the end-date the same as under the current scheduling order, and permit an orderly procession towards trial in April or early May, recognizing the expiration of the 30-month stay at the end of June and the Court's stated desire to avoid any PI proceedings. Please let us know if we can agree on this schedule, apart from whether further hydrates briefing may occur.

Very truly yours,

A handwritten signature in black ink that reads 'Mark Boland'. The signature is written in a cursive, slightly slanted style.

Mark Boland

cc: Counsel on email distribution list

# EXHIBIT B



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**Mark Boland**

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December 19, 2012

**Via Email**

Joshua I. Rothman, Esq.  
FITZPATRICK, CELLA, HARPER & SCINTO  
1290 Avenue of the Americas  
New York, NY 10104-3800

Re: *AstraZeneca AB et al. v. Hanmi USA, Inc. et al.*,  
Civil Action No. 11-00760 (JAP)(TJB)

Dear Josh:

Further to our letter of December 13, 2012, we are disappointed that we have not heard back from you on our proposal for the expert discovery schedule. Since Judge Bongiovanni told us to promptly confer and get back to her on the schedule, we attach a draft of a proposed joint letter reflecting the schedule we proposed to you last week. If we do not have your position on the proposed expert discovery schedule set forth in the attached letter today, we plan to submit the letter on behalf of Hanmi tomorrow morning.

Any other issues are separate from, and do not impact, the expert discovery schedule on which we were instructed to revert as soon as possible.

Very truly yours,

Mark Boland

cc: Counsel on email distribution list



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December 20, 2012

**VIA ECF & FEDERAL EXPRESS**

Honorable Tonianne J. Bongiovanni, U.S.M.J.  
U.S. District Court for the District of New Jersey  
Clarkson S. Fisher Building & U.S. Courthouse  
402 East State Street  
Trenton, New Jersey 08608

**DRAFT JOINT LETTER**

**Re: *AstraZeneca AB, et al. v. Hanmi USA, Inc., et al.*  
Civil Action No. 11-cv-0760 (JAP)(TJB)**

Dear Judge Bongiovanni:

This firm, along with Sughrue Mion, PLLC, represents the Hanmi Defendants ("collectively Hanmi") in the above-captioned action. The Parties jointly respectfully submit this letter following the November 28, 2012 conference call with Your Honor and the Court's subsequent December 12, 2012 Opinion and Order on claim construction (D.I. 257, 258).

The Parties propose the following schedule for expert discovery:

January 7, 2013 - Opening expert reports  
January 28, 2013 - Responsive expert reports  
February 11, 2013 - Rebuttal expert reports  
March 4, 2013 - Expert depositions end

The Parties ask that Your Honor amend the current schedule (D.I. 230) by indicating that the above expert discovery schedule is "so ordered."

Further, in light of the Court's stated goal of an April or early May trial in view of the expiration of the 30-month stay on June 29, 2013, the Parties respectfully request the Court's assistance in firming up the trial date and remaining pretrial dates in accordance with Judge Pisano's calendar, so that appropriate logistical arrangements for trial can be made.

Respectfully,

Mayra V. Tarantino



Honorable Tonianne J. Bongiovanni, U.S.M.J.

December 20, 2012

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MVT:emp

cc: Counsel of Record (via ECF)

**SO ORDERED** this \_\_\_\_\_ day of December, 2012

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Tonianne J. Bongiovanni, U.S.M.J.

# EXHIBIT C



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**Renita S. Rathinam**

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December 20, 2012

**Via Email**

Joshua I. Rothman, Esq.  
FITZPATRICK, CELLA, HARPER & SCINTO  
1290 Avenue of the Americas  
New York, NY 10104-3800

Re: *AstraZeneca AB et al. v. Hanmi USA, Inc. et al.*,  
Civil Action No. 11-00760 (JAP)(TJB)

Dear Josh:

This responds to several recent communications to our team.

As a preliminary matter, we are disappointed by your refusal to directly respond to our December 13 and 19 proposals concerning the expert discovery schedule in this case. Given Judge Bongiovanni's directive to promptly propose a schedule, you left us no choice but to proceed unilaterally.

With respect to your email to Mark Boland asking to meet and confer together with Mylan's counsel, the Court made clear in our November 28 phone conference that Judge Pisano is not inclined to try the Mylan and Hanmi cases together. The Court's *Markman* rulings now emphasize the further distinctions between the *Hanmi* and *Mylan* cases, as you are well aware. We have no intention of submitting any correspondence to the Court jointly with Mylan, or meeting and conferring together with you and Mylan's counsel since there are no joint issues on the table.

With respect to your inquiry regarding pursuit of a deposition of Dr. Kohl through Hague-type proceedings in Germany, our position is squarely set forth in our last communication on this issue with you dated December 11, 2012. Pursuant to the Hague Convention, a German national unwilling to appear voluntarily for deposition, as is Dr. Kohl, is not subject to compulsory attendance. The limited rights to take discovery in Germany of an unwilling German national in U.S. civil litigation fall far short of the deposition Judge Bongiovanni ordered that Hanmi is entitled to. As you may know, attempts to compel the attendance of an unwilling German citizen for a U.S. style deposition in Germany can subject the requestor to criminal liability. Therefore, the prior Kohl transcript is clearly inadmissible since your inability to produce Dr. Kohl for deposition denies us the fundamental right of cross examination. Your suggestion that any dates in this case need to be deferred based on the Kohl issue is, frankly, way



Joshua I. Rothman, Esq.  
December 20, 2012  
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out of line and a transparent attempt at yet another manufactured ground of delay. For all of the reasons we have told you, Hanmi cannot, and thus will not, proceed under the Hague Convention with respect to a cross examination deposition of Dr. Kohl. Should you seek to have the transcript admitted despite the above, we will object and move to preclude as necessary.

With respect to your recent email request to Mike Dzwonczyk for a meet and confer on your belated 30(b)(6) topics and discovery requests, we do not see any need to meet and confer at all. As our December 13 letter to you made clear, fact discovery closed long before these requests and the discovery you served was not only out of time but also unaccompanied by any of the required procedural prerequisites to serving belated discovery. Moreover, the 30(b)(6) topics fail to seek information relevant to any issue in this case.

We continue to have no objection to you deposing Parexel out of time and supplementing your submissions, if necessary.

Very truly yours,

A handwritten signature in blue ink, appearing to read 'Renita S. Rathinam', with a long, sweeping flourish extending to the right.

Renita S. Rathinam

cc: see email distribution

# EXHIBIT D

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December 13, 2012

Via Email

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Re: *AstraZeneca AB et al. v. Hanmi USA, Inc. et al.*,  
Civil Action No. 11-00760 (JAP)(TJB)

Dear Josh:

We write in response to your letter of December 4, 2012.

First, there is no discovery issue raised by Hanmi's November 30 disclosure under L. Pat. R. 3.6(j), which requires that correspondence to the FDA be provided to you within 7 days of its filing. Fact discovery in this case closed on November 20, 2012, and nothing in Hanmi's November 30 disclosure belatedly raises a fact discovery issue.

Second, Hanmi did not "admit infringement" of claims 8 and 9 of the '504 patent, as you stated. Rather, you know very well that Hanmi's proposed products do not contain the neutral form of (-)-omeprazole, and Hanmi's Notice Letter to AstraZeneca of December 29, 2010 under 21 C.F.R. § 314.95 (HAN0026234-HAN0026278) and the ensuing litigation record makes clear that Hanmi does not infringe Claims 8-9. Of course, the issue is moot because Claims 8-9 are not asserted in this litigation. Mark Boland advised that in your phone conference of December 5, you clarified that AstraZeneca is not seeking to assert Claims 8-9, consistent with all of your positions of record and representations to the Court. Rather, you advised during the call that any purported "admissions" with respect to Claims 8-9 were to be used in support of your allegations that Hanmi will induce infringement of *the method aspects* of Claims 6, 7 and 10 of the '504 patent - not the product aspects of those claims.

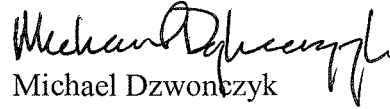
Yet nowhere in either of AstraZeneca's initial or amended infringement contentions does AstraZeneca allege that Hanmi practices the method aspects of Claims 6, 7 and 10 of the '504 patent based on a theory that there has been an "admission" regarding Claims 8-9 in an October, 2010 document submitted to the FDA. As such, your post-discovery letter of December 4 and your comments to Mr. Boland raise an entirely new theory of infringement, based on information you have had for almost two years.



Joshua I. Rothman, Esq.  
December 13, 2012  
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Because fact discovery has closed and the new theory you raise has not previously been identified and is belated, Hanmi will not provide a witness in response to AstraZeneca's new Rule 30(b)(6) Notice of Deposition and will not produce any additional documents. See concurrently transmitted Responses and Objections to AstraZeneca's Notice of Deposition under Rule 30(b)(6). Hanmi will also seek to preclude the introduction of any evidence relating to AstraZeneca's new infringement theories.

Very truly yours,

  
Michael Dzwonczyk

cc: (email distribution list)